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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,860	11/17/2003	Constance Neely Wilson	5623-10	1884

826 7590 10/09/2007

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,860	WILSON, CONSTANCE NEELY	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,10 and 23-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,8,10 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 10 July, 2007. Claims 1, 3-5, 7, 8, 10, and 23-28 are pending in the instant application.

37 C.F.R. § 1.98

The information disclosure statement filed 10 July, 2007, has been placed in the application and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claims 2 and 6 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot in view of applicant's amendment.

New claims 23 and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims

must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims reference an "immune system disorder" comprising HIV infection. HIV infection is not an immune system disorder. The clinical sequelae associated with HIV infection leads to the development of acquired immune deficiency syndrome, or AIDS. AIDS is an immune system disorder. Appropriate correction is required.

Applicant argues that it is permissible to act as one's own lexicographer. However, when the term precludes one skilled in the art from ascertaining the true claim breadth, a rejection under this statute is appropriate. Applicant's reference to an immune system disorder comprising HIV is both confusing and inconsistent with basic infectious disease principles. Accordingly, the rejection is proper and hereby maintained.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 3-5, 7, 8, 10, and 23-28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (1) The breadth of the claims; (2) The nature of the invention; (3) The state of the prior art; (4) The level of one of ordinary skill; (5) The level of predictability in the art; (6) The amount of direction provided by the inventor; (7) The existence of working examples; and (8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

The disclosure fails to adequately address a number of these factors as follows:

1) Adenosine deaminase deficiency-dependent severe immunodeficiency disease (ADA-SCID) results from a genetic defect in the ADA gene. It is not readily manifest that simply providing a therapeutic agent would correct this deficiency since it fails to restore ADA activity. Most therapeutics approaches have been directed toward restoring the enzymatic activity of this gene (Onodera *et al.*, 1999; Alessandro *et al.*, 2003; Javier *et al.*, 2004).

2) It is not readily manifest that A_1 adenosine receptor antagonists or P_{2x} purinoceptor antagonists would be efficient at inhibiting viral replication or reducing the viral burden associated with HIV infection. Nothing in the literature provides any nexus between HIV viral replication and A_1 adenosine

receptor antagonist or P_{2x} purinoceptor antagonist administration. HIV is a difficult virus to treat because of the high number of virions generated per day and the ability of the virus to reside throughout the lymphatic compartment, often in a latent state (Ho *et al.*, 1995).

3) The disclosure fails to provide any working embodiments demonstrating that ADA-SCID was effectively treated with A_1 adenosine receptor antagonists or P_{2x} purinoceptor antagonists.

4) The disclosure fails to provide any working embodiments demonstrating that A_1 adenosine receptor antagonists or P_{2x} purinoceptor antagonists can reduce the viral burden associated with HIV infection and provide any meaningful clinical effect.

5) The state-of-the-art as it pertains to the treatment of ADA-SCID has been relatively unpredictable (Onodera *et al.*, 1999; Alessandro *et al.*, 2003; Javier *et al.*, 2004). Some gene therapy trials have shown promise, but once again, there is no data to suggest that A_1 adenosine receptor antagonists or P_{2x} purinoceptor antagonists would be effective at restoring ADA activity.

6) The state-of-the-art as it pertains to the generation of HIV antivirals can be characterized by unpredictability (Gait and Karn, 1995; D'Souza et al., 2000). HIV antivirals generally are targeted toward specific viral gene products and effectively inhibit the functions or activities of said gene products. However, there is nothing to suggest that A_1 adenosine receptor antagonists or P_{2x} purinoceptor antagonists would effectively inhibit viral replication.

7) The disclosure fails to provide sufficient guidance pertaining to the structures and binding activities of different A_1 adenosine receptor antagonistic antibodies or P_{2x} purinoceptor antagonistic antibodies. The disclosure fails to demonstrate

that high affinity antibodies can be generated with the desired activities. The disclosure fails to provide any guidance pertaining to those molecular determinants that would prove useful targets to antibody binding.

When all the aforementioned factors are considered *in toto*, the skilled artisan would reasonably conclude that undue experimentation would be required to practice the claimed invention.

Applicant traverses and submits that the specification fully enables the claimed subject matter. Applicant relied upon a number of references in support of this assertion (Sarzynska, 2003; Sipka, 1988; McElhinny *et al.*, 1995; Asin *et al.*, 1999; and Unutmaz *et al.*, 1998). However, these references fails to support applicant's position. First, Sarzynska (2003) simply identifies a viral A-rich region that mediates viral RNA binding to tRNA. The virus does not normally enter cells through a genomic RNA/cellular receptor interaction so this reference is not directly relevant. Second, Sipka (1988) noted that A2 receptor stimulation, NOT antagonism, reduced HIV-related cytopathicity *in vitro*. Thus, it is not readily manifest how antagonizing the adenosine receptors would inhibit viral replication. Third, McElhinny *et al.* (1995) simply report that HIV infection activates NF-Kβ expression. There is no discussion of adnosine receptor influence or utilization. Fourth, Asin *et al.* (1999) report that NF-Kβ activation is NOT required for viral persistence, further confusing the issue. Finally, Unutmaz *et al.* (1998) demonstrate that HIV-1 predominately utilizes CD4/CCR5 or CD4/CXCR4 receptor interactions. The virus does not regularly or frequently utilize G-protein-coupled receptors. Moreover, applicant's

response failed to proffer any objective scientific evidence addressing the caveats discussed *supra*. Accordingly, the rejection is proper and hereby maintained.

Finality of Office Action

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

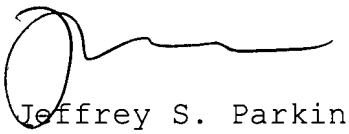
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related

correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

30 September, 2007